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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,985	02/26/2004	Chuang Chun Chiueh	CHIU3034/EM	2667

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,985	CHIUEH, CHUANG CHUN	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9,11-17 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,11-17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and response filed January 22, 2007 is acknowledged and entered. Please note that the response to the Notice of Non-Compliant Amendment is acknowledged and the error has been corrected. Claims 1-4, 9, 11-17 and 19 remain pending and under examination.

Interview Summary

2. In the previous Office action of August 23, 2006, the Office stated that Applicant's representative took great liberties in summarizing the content of the interview of April 12, 2006 in the response filed April 19, 2006. Particularly, Applicant's representative made statements on behalf of the examiner regarding the art rejections of record. Further, the documents that the examiner faxed to Applicant's representative on April 12, 2006 following the telephone conversation were not made of record and were merely for informational purposes. In Applicant's response filed April 19, those documents (not of record) are addressed as if the references are of record.

In the response filed January 22, 2007, Applicant's representative notes that Applicant's summary of the interview represents an accurate account of what transpired during the telephone interview. Applicant's representative invites the examiner to specifically identify those portions of the summary which were perceived as inaccurate as well as provide the examiner's account of the telephone interview.

In response, the examiner kindly points Applicant's representative to the statements made in the Office action of August 23, 2006, which specifically pointed out the portions of

Applicant's summary of the interview that were not accurate. As to the examiner's account of the events that transpired during the interview, a summary of the interview was provided to Applicant that was mailed April 14, 2006. If Applicant did not receive a copy of this interview summary, it may be viewed on Public PAIR. The summary is reproduced below for Applicant's convenience.

> Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussed the enablement rejection over "prevents viral infection". The examiner suggested some alternatives to overcome the rejection. Also discussed the art rejections, specifically, percentages of the elements claimed versus those in the prior art. The examiner and applicant's representative agreed to further research the natural concentrations of the claimed elements in spirulina. Should the natural concentrations/percentages of spirulina's contents read on the claimed composition, applicant may consider amending the claims to specify a percentage range that will distinguish over the prior art.

Claims Summary and Interpretation

3. The claims as amended are drawn to an oral agent that inhibits influenza virus infection. In the embodiments of claims 1, 2, 9, 11-17 and 19, the agent comprises a water-soluble formula having all of the following components:

- 3%-45% C-phycocyanin
- 1%-15% allophycocyanin
- 96%-40% spirulina growth factor (SGF)

The agent may also be an enteric-coated formula, though no ingredients are recited for this particular formula, except in claim 9. Claim 9 indicates that the enteric-coated formula comprises 10% to about 30% water-soluble formula, 15% solid additive and 75% to about 55% vegetable oil. The water-soluble formula and the enteric-coated formula (no ingredients recited) are used separately or in combination.

In the embodiments of claims 3 and 4, the oral agent comprises the combination of a water-soluble formula and enteric-coated formula. The ratio of the water-soluble formula to the

enteric-coated formula is 1:1 to about 1:10 by weight, more specifically, 2:9.8 by weight. The enteric-coated formula has no recited ingredients. The water-soluble formula comprises at least one ingredient selected from the following:

- C-phycocyanin
- Allophycocyanin
- SGF
- Combinations of C-phycocyanin, allophycocyanin and SGF

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained. Applicant's arguments are addressed in paragraph number 6.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, specifically because the Office asserted that

one would not know how to obtain SGF, is maintained. Applicant's arguments are addressed in paragraph number 6.

6. Applicant's arguments with regard to the rejections under 35 U.S.C. 112, first and second paragraph, have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

- Applicant points to page 3, lines 10-20 of the instant application for a definition of SGF. That portion of the specification is reproduced below:

> Spirulina growth factor (SGF) is the essence of blue green algae, which contains nucleic acids, nucleotides, small molecule proteins, sulfur-containing polysaccharides, water-soluble vitamins and minerals. SGF is rich in polysaccharides which can boost immune system and possess anti-viral and anti-tumor activities. Sulfur-containing polysaccharides are found by Harvard University to be effective against AIDS and many other viruses. (Journal of Phycology 1993; 29: 125-130, Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 1998; 18: 7-12, International Immunopharmacology. 2002; 2:423-434).

- In response to Applicant's remarks, the Office has considered the specification's teachings. While SGF is indicated as containing nucleic acids, nucleotides, small molecule proteins, sulfur-containing polysaccharides, water-soluble vitamins and minerals, the specification does not disclose anything specific. The specification does not teach which small molecule proteins, which sulfur-containing polysaccharides, which water-soluble vitamins, or which minerals are in SGF.

Without this information, how would one of skill in the art know that they are in possession of the same SGF that Applicant uses?

- Applicant argues that one of ordinary skill in the art at the time of filing the instant application would understand the definition of SGF. Applicant points to a product produced in Taiwan, by the Far East Microalgae Co., Ltd of Taipei. The SGF powder and liquid are described as a hot water extract of Spirulina. A product description from the company's website is attached to this Office action and a portion of it is reproduced below from the following website:

http://www.femico.com.tw/Organic-Drinks-e.html

3. Spirulina Growth Factor(SGF)
SGF is the hot water extract of Spirulina. It is a mixture of all the water-soluble ingredients in Spirulina. SGF is composed of nucleic acids, peptides, water soluble vitamins and minerals. The recent studies found Spirulina extract is able to reduce viral replication. It is very good for human immune system.

Applications of SGF:
1) Used as the health foods or drinks: SGF powder may be filled in capsules for direct food supplements, or as an ingredient in health food/drinks.
2) For cosmetics additives as skin care applications.
3) For biochemistry to increase the growth rate of some micro-organism.
4) Increase body metabolism and immune system ability.
5) May have the anti-oxidation effect and delay skin aging.
6) SGF can be applied for the infant milk products due to its rich nucleic acids. The new trend of infant milk powder is emphasizing nucleic acids.

SGF Is available as:

★ Powder: OD-2000, OD-4000 and OD-5000
★ Liquid: OD-200 and OD-400

- The Office has considered what one would know about SGF at the time of filing. Given evidence such as from the Far East Microalgae product description page, one would know not know which peptides, water-soluble vitamins and minerals

are present in SGF. Without this knowledge, how would one of skill in the art know that the SGF obtained from any variety of sources (health food stores, homemade extracts, etc.) is the same SGF that Applicant is using? Because the contents of the SGF are so loosely defined, the metes and bounds of what constitutes SGF cannot be determined.

- Applicant also notes that the method of extracting SGF is as follows: a) add 100g blue green algae powder into 900 ml water, mix evenly, b) steam sterilize the mixture at 120 degrees Celsius for 60 minutes, c) cool the mixture and centrifuge the mixture at 8000 rpm for 30 minutes and d) collect the supernatant which contains SGF. Applicant also points to an absorption spectrum of SGF powder, which defines the structure of SGF.
  - In response, while it is useful to know how to prepare SGF, this explanation is not disclosed in the specification. If this is the sole method by which SGF may be made for purposes of the instant invention, then even the blue-green algae powder must be questioned. What components are in the blue-green algae powder, and how was the blue-green algae powder prepared? Without this information, the contents of blue-green algae powder may vary from source to source. This is why it is critical to know the exact contents of SGF such that one of skill in the art would know that it is the same SGF that Applicant uses.
  - The absorption spectrum of SGF powder does not disclose which nucleic acids, small molecule proteins, vitamins, minerals, and sulfur-containing

polysaccharides are present. Another consideration is, what was the source of the SGF powder used for this absorption spectrum?

- In view of the uncertainty of the contents of SGF, the Office maintains its position that the contents of SGF are not adequately defined by the specification, nor are the contents of SGF disclosed in literature such as the Far East Microalgae product description pages such that one would be apprised of the specific components present in the SGF used by Applicant.

7. ***The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained.*** The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims as amended encompass agents that are capable of inhibiting influenza virus infection in any host. The agents are those described above, which contain various assigned amounts of C-phycocyanin, and/or allophycocyanin, and/or Spirulina growth factor (SGF). Inhibition of influenza infection is the inhibition of an influenza virion entering a host cell in a host. In order for inhibition of influenza infection to be demonstrated, a suitable animal model must be challenged with influenza virus after having been previously treated with the agent that Applicant claims is capable of inhibiting infection. At the time of filing, Applicant did not show experiments or literature that supports the instantly claimed composition to be capable of inhibiting one influenza virion from entering one host cell in a host, or even *in vitro*. Without

this information, one of skill in the art would not know how to inhibit influenza viral infection in any host. One of skill in the art would not expect C-phycocyanin and/or allophycocyanin and/or Spirulina growth factor to inhibit influenza virus entry without having seen proof that it works in at least an acceptable animal model of influenza virus infection.

While the specification, page 2, line 17 through page 3, line 20, discloses that phycocyanin and allophycocyanin are capable of inhibiting enterovirus and influenza virus, the specification does not demonstrate that the instantly claimed phycocyanin, allophycocyanin and SGF compositions having the claimed concentrations are capable of inhibiting influenza virus. In order for the instant claims to be enabled, the inhibition of virus entry with the claimed concentrations of phycocyanin, allophycocyanin or Spirulina growth factor must be demonstrated. While Applicant does not need to show the mechanism behind any anti-viral inhibitory activity of any or all of these compounds, some evidence is required to enable the instant claims. Therefore, the claims as written are not enabled for their intended use as an inhibitory agent against influenza infection.

Given the breadth of the claims (encompassing a broad range of concentrations of compounds), the nature of the invention (inhibiting an influenza virion from entering a host cell of a host), the state of the art (phycocyanin and allophycocyanin being capable of inhibiting influenza virus), the high level of skill in the art and the low level of predictability evidenced by no working examples of influenza virus inhibition *in vitro* or *in vivo*, it would require undue experimentation to make the claimed compositions that have the ability to inhibit influenza infection.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

- Applicant notes that the claims are drawn to a composition, not a method of inhibiting influenza viral infection. Applicant submits that the issue of enablement does not go to whether one of ordinary skill in the art would know how to make and/or use a method of inhibiting influenza infection, but rather whether the specification enables one to make and/or use the composition claimed in the instant application.
  - In response to Applicant's argument, the Office recognizes that the claimed compositions are intended for use as an inhibitory agent against influenza. Because the claims recite the intended use, the enablement of the intended use must be analyzed for adequate enablement by the specification. If the claims did not recite the intended use, then the enablement rejection over inhibiting influenza virus would be a non-issue.
- Applicant argues that one of ordinary skill in the art at the time of the invention would have known how to use the composition based on the specification without the need for undue experimentation. Applicant provides experimentation on mice that would have been considered routine in the art. Applicant's *in vivo* data shows the oral administration of a prepared oral agent in various control and experimental groups of mice. Applicant's data shows that mice that were administered influenza type A virus along with the oral agent developed influenza symptoms, but did not die and eventually recovered. Mice that were not administered the oral agent but exposed to influenza type A died. Applicant concludes that the oral agent according to the

present invention can totally prevent death of mice infected with type A influenza virus.

- In response to Applicant's arguments, the evidence would be more appropriately presented in a declaration from someone in a position to corroborate the source of the experiments, how were they carried out, and a nexus to the application as filed/claims. When any claim of an application is rejected, any evidence submitted to traverse the rejection on a basis not otherwise provided for must be by way of an oath or declaration under 1.132.
- Regardless of the lack of a declaration, the Office has considered the data and found it to be unpersuasive. For instance, the oral agent composition is not disclosed. There are several compositions instantly claimed, however, the data presented in Applicant's remarks does not set forth which particular composition(s) was used (water-soluble formula, enteric-coated formula, components, percentages of components, ratios of the components, etc.). In summary, the evidence must be more substantive in order for a reasonable conclusion to be drawn and evaluated.

- Applicant argues that the specification sets forth both an example for preparing the oral composition and also an example for adding the composition to a drink, see pages 8-10. Applicant argues that the compositions are used as oral compositions, taken by mouth as a capsule or added to a drink or food. Applicant asserts that the Office has not provided a reason as to why it doubts the objective truth of the statements contained in the specification with respect to making the composition.

- In response to Applicant's arguments, the Office acknowledges that one can formulate the instant compositions and add them to drinks and food to be ingested. However, the rejection is based on the intended use recited in the claims. One would not be able to make a composition that has the ability to inhibit influenza infection, nor use a composition for inhibiting influenza infection, lacking substantial evidence.

- Applicant argues that phycocyanin has already been proven to inhibit the infection of influenza viruses at concentrations greater than 0.04 μM. Applicant asserts that this evidence serves as an enabling disclosure that would allow one to use the claimed invention, which contains two types of phycocyanin as at least 4% and as much as 60% of the claimed composition, to inhibit influenza virus.
  - In response to Applicant's arguments, the issue at hand is whether C-phycocyanin, allophycocyanin, and/or SGF are able, alone or in combination in various formulations, can inhibit influenza infection. Applicant's own work, described in the specification (pages 2-3 which reference US Patent 6,346,408) discloses, generally, that phycocyanin inhibits influenza virus replication. Pages 2-3 of the specification do not distinguish between C-phycocyanin and allophycocyanin. The referenced patent pertains only to allophycocyanin, with no teaching about determining the various concentrations of C-phycocyanin. Therefore, although Applicant states that phycocyanin inhibits influenza infection, the referenced patent only discloses allophycocyanin. Clearly, the claims encompass compositions outside of this single disclosure. Even the patent does

not disclose which concentrations of allophycocyanin are required to inhibit influenza. The patent is directed to methods of discovering the concentration required.

- Applicant asserts that the Office has failed to provide objective evidence to support the supposed lack of enablement. Applicant finds that the Office has presented broad, unsupported statements without providing references in support of each allegation. Applicant also finds that the Office has presented an abbreviated Wands analysis at page 4 and 5 of the Office action.
  - In response to Applicant's assertions, the Office has set forth what is required to demonstrate efficacy of a composition that inhibits influenza virus infection. Inhibition of infection must be demonstrated with challenge experiments in an acceptable animal model. Without this information, one of skill in the art would not progress to clinical trials. Although the PTO does not use the same standards as the FDA, some evidence is required so that one would reasonably expect that the claimed compositions would indeed inhibit influenza. The specification does not set forth any experimental data regarding phycocyanin (C-phycocyanin or allophycocyanin), nor any data regarding SGF.
  - Further, although Applicant's opinion is that the Wands analysis is abbreviated, the factors that must be considered are present in the analysis. References are not required to support an enablement rejection, as Applicant is well aware. Therefore, the rejection is maintained for reasons of record.

Conclusion

8. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The

examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 3/28/07

STACY B. CHEN
PRIMARY EXAMINER